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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,120	11/29/2004	Masaru Yamakoshi	1516-0126PUS1	3292
2292 BIRCH STFW	7590 12/04/2007 ART KOLASCH & BIRCI	EXAMINER		
PO BOX 747		MARTIN, PAUL C		
FALLS CHUR	CH, VA 22040-0747		ART UNIT	PAPER NUMBER
	•	1657		
			NOTIFICATION DATE	DELIVERY MODE
			12/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

		Application	n No.	Applicant(s)	·				
Office Action Summary		10/509,120)	YAMAKOSHI ET AL.					
		Examiner		Art Unit					
		Paul C. Ma	rtin	1657					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply									
	ORTENED STATUTORY PERIOD FOR REPLY	/ IS SET TO) EXPIRE 3 MONTH	S) OR THIRTY (30) DAYS					
WHIC - Exter after - If NC - Failu Any	CHEVER IS LONGER, FROM THE MAILING DATE INSTITUTE TO THE WAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING	ATE OF THI 36(a). In no ever vill apply and will , cause the appli	IS COMMUNICATION of, however, may a reply be tin expire SIX (6) MONTHS from cation to become ABANDONE	N. nely filed the mailing date of this communication. (D. (35 U.S.C. § 133).					
Status									
1)⊠	Responsive to communication(s) filed on 21 Se	eptember 20	<u>007</u> .						
, —	This action is FINAL. 2b)⊠ This action is non-final.								
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
	closed in accordance with the practice under E	x parte Qua	<i>iyle</i> , 1935 C.D. 11, 4	53 O.G. 213.					
Disposit	ion of Claims								
4)🖂	Claim(s) 1-9,13,14,28 and 31-33 is/are pending	g in the app	lication.						
	4a) Of the above claim(s) is/are withdraw	wn from con	sideration.						
· —	Claim(s) is/are allowed.								
·	Claim(s) <u>1-9,13,14,28 and 31-33</u> is/are rejected	d.							
•	Claim(s) is/are objected to.	r election re	auirement						
اـــا(٥	8) Claim(s) are subject to restriction and/or election requirement.								
Applicat	ion Papers								
, —	The specification is objected to by the Examine								
10)⊠ The drawing(s) filed on <u>28 September 2004</u> is/are: a)⊠ accepted or b)☐ objected to by the Examiner.									
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
اــا(۱۱	The bath of declaration is objected to by the Ex	Kammer. NO	e the attached Office	Action of form F10-132.					
Priority (under 35 U.S.C. § 119								
12)	Acknowledgment is made of a claim for foreign	priority und	er 35 U.S.C. § 119(a)-(d) or (f).					
a)	☐ All b)☐ Some * c)☐ None of:								
	1. Certified copies of the priority document			ian Na					
	2. Certified copies of the priority documents3. Copies of the certified copies of the priority								
	application from the International Bureau			sa iii tiiis ivationai otage					
* 5	See the attached detailed Office action for a list			ed.					
Attachmer	nt(s)								
_	ce of References Cited (PTO-892)		4) Interview Summary						
3) 🔲 Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date		Paper No(s)/Mail D 5) Notice of Informal F 6) Other:						

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DETAILED ACTION

Claims 1-9, 13, 14, 28 and 31-33 are pending in this application and were examined on their merits.

The rejection of Claims 1-5, 8, 9, 14, 30 and 31 under 35 U.S.C. § 102(b) as being anticipated by Takatsuma *et al.* (JPO 2001190299A) has been withdrawn due to the Applicants amendments to the Claims filed 09/21/07.

The rejection of Claims 1-9, 14, 18-20, 27, 28, 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Takatsuma *et al.* (JPO 2001190299A) in view of Tazoe *et al.* (US 6,309,852 B1) has been withdrawn due to the Applicants amendments to the Claims filed 09/21/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 13, 14, 28 and 31-33 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Newly amended claims 1 and 31 contain the new limitations wherein concentration(s) of myo-inositol at characteristic values or higher than characteristic values of 0 to 20 micrograms myo-inositol per milligram creatinine when measured as an increasing amount of myo-inositol excreted in the urine after 75 grams glucose load is indicative of a subject having mild impaired glucose tolerance or an insulin secretory defect. One of ordinary skill in the art would not be able to use the instant invention because no time periods are specified in the method, though the disclosure repeatedly refers to time limits for collecting and analyzing specimens (See Specification, Pg. 10, Lines 1-3 and Table 3). Obviously, the invention relies on the performance of the method at critical time periods as performance of the method at a time of 24 hours or even several days after a 75 gram glucose load would miss the myo-inositol excreted in the urine.

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Further, the reference refers to the comparison of myo-inositol per milligram creatinine, yet nowhere in the instant method is a measurement of creatinine performed. One would not be able to use an invention requiring a comparison to a quantity which was never determined. Finally, the concentration of myo-inositol is referred to by characteristic values or higher than characteristic values of 0 to 20 micrograms per mg creatinine. The characteristic values are never explained or explicitly defined in the methods and the value which is higher than the characteristic values of 0 to 20 micrograms per mg creatinine is essentially a limitless value extending into infinity beyond 20 micrograms per mg creatinine. One of ordinary skill in the art at the time of the invention would not be able to practice the invention without knowing what time periods are required to perform the method, a step of measuring the creatinine level as a basis for comparison and without knowing what the characteristic values are and what the definition of the upper limits of the characteristic values specifically encompass. Claims 2-9, 13, 14, 28, 32 and 33 are rejected as being dependent upon rejected claims 1 and 31.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-33 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites the limitation "the urine" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 32 and 33 are rejected as being dependent upon rejected Claim 31.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin Examiner Art Unit 1657

11/23/07

JON WEBER
SUPERVISORY PATENT EXAMINER